REMARKS/ARGUMENTS

By this Amendment, claim 24 is amended. Claims 22 and 24 are pending.

Rejection under 35 U.S.C. § 103(a)

The Examiner has rejected claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Yamamoto in view of Cooke, Quirk, Lichenstein, Murphy, and Luckow. Applicant respectfully traverses this rejection.

An ordinarily skilled artisan would not have had a reasonable expectation of successfully reaching the claimed invention based upon the teachings in the references cited by the examiner. To begin with, Yamamoto does not teach the cloning of the Gc protein into a baculovirus vector and Luckow teaches only generic applications regarding the use of baculoviruses as vectors. Moreover, the Examiner does not show how or where Luckow teaches that a baculovirus vector could be successfully employed to express the GcMAF protein in all insect cells. The mere fact that Luckow describes several successful examples comprising the use of a baculovirus vector to express certain proteins in insect cells, without any showing that such proteins are substantially analogous to, and reasonably predictive of, GcMAF, does not sustain the Examiner's burden of showing that an ordinarily skilled artisan would have been motivated to have made the proposed combination of reference teachings, and would have had a reasonable expectation of success in doing so. See, e.g., *In re Vaeck*, 20 USPQ2d 1438, 1443 (Fed. Cir. 1991).

In fact, none of the cited references show how to clone the GcMAF or a substantially analogous protein into a baculovirus vector. Cooke discloses both the nucleotide and amino acid sequences of the vitamin D binding protein although all of the cloning was performed with standard plasmid vectors in *E. coli* not a baculovirus. Lichenstein discloses the cloning of afamin (AFM), a member of the human serum albumin protein family; however, it provides no guidance on how to clone the GcMAF protein of the present invention. Also, Lichenstein neither mentions nor teaches the use of baculovirus vectors for cloning and expression purposes. The Examiner referred to Lichenstein as disclosing that host cells from mammals, prokaryotes, fungi, yeast, insects and the like are used for the recombinant protein expression of AFM. (column 13, lines

52-55). However, merely stating that something is possible does not render it so. This statement was made as a general comment in the background section of this patent and there is no evidence in Lichenstein to support it. The only type of cloning that is performed in Lichenstein is with the use of a bacterial expression vector, not a baculovirus vector. Also, Quirk teaches how to express and purify human serum albumin in brewer's yeast. As such, it provides no teaching of how to clone GcMAF or any members of the human serum protein albumin (ALB) family with the use of a baculovirus vector. Also, the Gc protein is O-glycosylated whereas all other members of the albumin family are not O-glycosylated. Therefore, the Gc protein is unique because it will not be processed like other members of the albumin serum protein family. Because of this difference in processing, eukaryotic baculovirus vectors are used exclusively for cloning the functional Gc protein. Prokaryotic vectors are used for the cloning of other members of the serum albumin family.

The Examiner also cites Murphy as providing vectors to express recombinant proteins during baculovirus infection. Specifically, Murphy discloses several baculovirus vectors that are useful in generating glycosylated proteins in the late term of infection. The Examiner pointed out that Murphy states that these vectors may be useful for the expression of a wide variety of proteins, including human blood factors. However, the only protein that Murphy expressed with this method is the gp120 HIV glycoprotein. Unlike the Gc protein, gp120 is not sialylated and there is no evidence in Murphy to suggest that a sialylated protein could be generated as easily due to the nature (tertiary structure) of these proteins. Taken together, these references do not provide the type of teaching that would cultivate confidence in a skilled artisan, and serve as the basis for a reasonable expectation of success in cloning the Gc protein in a baculovirus vector. Therefore, Applicants respectfully request that the Examiner withdraw his rejection.

Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claim 24 as allegedly being unpatentable over Yamamoto in view of Cooke, Quirk, Lichenstein, Murphy and Luckow as applied to claim 22 above, and further in view of Sambrook. Applicant respectfully traverses this rejection.

Applicants refer the Examiner to the arguments made above regarding Yamamoto, Cooke, Quirk, Lichenstein, Murphy and Luckow. Examiner states that Sambrook teaches that the sequence of an individual DNA molecule cloned from a PCR amplified pool is unreliable and, therefore, should be confirmed by sequencing. However, because of possible translational infidelity, the wild type Gc1 peptide needs to be confirmed by sequencing of the cloned protein. Applicant has amended claim 24 to clarify this point. Also, Applicant points out that the method of claim 24 does not utilize PCR. In fact, Applicant does not even discuss the use of PCR in the application. Therefore, Sambrook does not relate to the instant invention and Applicant respectfully request that the rejection be withdrawn.

Rejection under 35 U.S.C. §112

The Examiner has rejected claim 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

In response to Applicant's previous argument, the Examiner states that although standard sequencing technology may have enabled the sequencing of a cloned Gc1 isoform and comparing the sequence obtained with the presently disclosed sequence at the time of Applicant's invention, the present specification does not describe this procedure. However, although Applicant does not specifically describe a protein sequencing protocol, one of ordinary skill in the art would know how to perform this procedure. Also, Applicant disclosed the amino acid sequence of the wild-type Gc protein. After sequencing the cloned protein one would be able to compare the sequenced protein or peptide to the wild-type amino acid sequence that is disclosed in the instant specification. Thus, Applicant respectfully requests that this rejection be withdrawn.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

July 4, 2005

By_____

Robert S. Silver
Registration No. 35,681
Customer No. 03000
(215) 567-2010
Attorneys for Applicant

Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.